



To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the claimant's attorney completes Part III if claimant is represented.

In November, 2003, claimant submitted a completed supplemental Green Form to the Trust signed by her attesting physician, Susan R. Jensen, M.D., F.A.C.C., F.C.C.P., F.A.C.P., F.S.C.A.I. Based on an echocardiogram dated August 19, 2002, Dr. Jensen attested in Part II of claimant's Green Form that Ms. James suffered from moderate mitral regurgitation and that she underwent surgery to repair or replace the aortic and/or

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3. (...continued)  
contributed to a Claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

mitral valve(s) following the use of Pondimin® and/or Redux™.<sup>4</sup>  
Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$696,987.<sup>5</sup>

In the report of claimant's echocardiogram, Dr. Jensen stated that Ms. James had "a significant central mitral regurgitation jet of at least 3+ into an enlarged left atrium with multiple other mitral regurgitation jets noted along the anterior and posterior leaflets with at least 5 jets of significance visualized with multiple smaller jets noted." Dr. Jensen, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

As the Trust does not contest claimant's entitlement to Level III benefits, the only issue before us is whether Ms. James is entitled to payment on Matrix A-1 or Matrix B-1. Specifically, the Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant when he or she was

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4. Dr. Jensen also attested that claimant suffered from a reduced ejection fraction in the range of 50% to 60%. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

diagnosed with mild mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.<sup>6</sup> See Settlement Agreement § IV.B.2.d.(2)(a).

In March, 2004, the Trust forwarded this claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram of August 19, 2002 demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Irani stated, "Mild [mitral regurgitation] by [transesophageal echocardiogram] with ratio likely 15%".

Based on Dr. Irani's finding that Ms. James only had mild mitral regurgitation on the echocardiogram of August 19, 2002, the Trust issued a post-audit determination that Ms. James was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup>

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6. The Screening Period ended on January 3, 2003 for an echocardiogram obtained independent of the Trust's Screening Program and ended on July 3, 2003 for an echocardiogram obtain through the Trust's Screening Program.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute  
(continued...)

In contest, Ms. James argued that there was a reasonable medical basis for Dr. Jensen's representation that Ms. James had moderate mitral regurgitation based on her August 19, 2002 transesophageal echocardiogram and other medical records. In support, Ms. James submitted letters from Dr. Jensen and Steven J. Mattleman, M.D., F.A.C.C. In her letter, Dr. Jensen confirmed that claimant's August 19, 2002 echocardiogram and a subsequent cardiac catheterization demonstrated "[m]oderately [s]evere 3+ [m]itral [r]egurgitation." Dr. Mattleman stated that he reviewed claimant's June 4, 2002 and August 19, 2002 echocardiograms and that they demonstrated severe mitral regurgitation and at least moderate regurgitation, respectively. Dr. Mattleman also included six still frames he said demonstrated his findings. Claimant further demanded that the Trust review the June 4, 2002 transthoracic echocardiogram she previously submitted. According to Ms. James, transthoracic echocardiograms allow precise measurements while transesophageal echocardiograms do not. Finally, claimant argued that the auditing cardiologist improperly applied the reasonable medical basis standard because he (1) substituted his own opinion, and (2) failed to account for inter-reader variability.<sup>8</sup>

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7. (...continued)  
that the Audit Rules contained in PTO No. 2807 apply to this claim.

8. In support of these arguments, claimant included excerpts from the transcript of the deposition of Michele Nanna, M.D., the affidavits of Arthur L. Caplan, Ph.D. and Scott L. Roth, M.D.,  
(continued...)



Following her contest, the Trust asked Joseph Kisslo, M.D., to review claimant's June 4, 2002 echocardiogram.

Dr. Kisslo concluded:

7. The size of Ms. James' alleged regurgitant jet was exaggerated by manipulating the echocardiography machine controls, specifically by using excessive color gain, color persistence by interpolation, and color pixels dominant over anatomy.

8. Backflow was included in the measurement of Ms. James' regurgitant jet area.

9. Ms. James' two-dimensional echocardiogram demonstrated image persistence. This inappropriate image persistence setting was evidence that true timing information was ignored by those responsible for the June 4, 2002 TTE.

10. In my opinion, Ms. James' June 4, 2002 TTE and the diagnosis based thereon grossly distorted the severity of mitral regurgitation. Ms. James' level of mitral regurgitation is trivial at most, mild....

The Trust then issued a final post-audit determination, again determining that Ms. James was entitled only to Matrix B-1, Level III Benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim of Ms. James should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the

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8. (...continued)  
and the declaration of Laurence S. Magder, Ph.D., M.P.H.

Special Master for further proceedings. See PTO No. 5245 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 12, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that her August 2002 echocardiogram demonstrated moderate mitral regurgitation. See Audit Rule 24. Ultimately, if we determine

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant raises the same arguments she made in contest. In addition, Ms. James submits an affidavit and letter from James D. Albert, M.D., F.A.C.S., the surgeon who performed her mitral valve replacement. Dr. Albert stated, "The degree of mitral insufficiency was confirmed by the presence of a large left atrium. The valve could not close properly and I would be very surprised if it did not leak significantly." Claimant further contends that Dr. Kisslo's affidavit is irrelevant because Dr. Kisslo: (1) did not state that the June 4, 2002 echocardiogram failed to conform to the Feigenbaum or Weyman texts, and (2) did not measure, but merely "eyeballed," the RJA/LAA ratio.

In response, the Trust argues that neither claimant nor her physicians address or rebut the specific findings of the auditing cardiologist, Dr. Irani. In addition, the Trust asserts that Dr. Albert's letter does not assist claimant because he does not give an opinion as to the level of her mitral regurgitation prior to surgery. The Trust also claims that the June, 2002 echocardiogram should be ignored because "machine setting



manipulations" exaggerated claimant's level of mitral regurgitation. Finally, the Trust contends that Dr. Irani correctly applied the reasonable medical basis standard in reviewing this claim and that the various affidavits and declarations submitted by claimant are either inadmissible or irrelevant.

The Technical Advisor, Dr. Vigilante, reviewed claimant's August 19, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding moderate mitral regurgitation. In particular, Dr. Vigilante that:

I reviewed Claimant's echocardiogram of August 19, 2002.... This study was of reasonable quality with the usual [transesophageal echocardiographic] views obtained. The left atrium appeared to be enlarged but the LAA cannot be measured on this study as this was an off axis view of the left atrium.... A narrow jet of mitral regurgitation was seen traveling into the mid portion of the atrium. This was particularly evident when taken at 0 degrees and 162 degrees. At 97 degrees and 46 degrees, several tiny jets of mitral regurgitation were noted which would be typical in these views in a patient with mitral regurgitation as these views demonstrate the coaptation line of the two mitral leaflets. There is minimal flow convergence in all of the views that evaluate mitral regurgitation. There is no wide jet of mitral regurgitation nor significant flow convergence. Therefore, this [transesophageal echocardiogram] demonstrates mild regurgitation.

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... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. when referring to the transesophageal echocardiogram study of August 19, 2002. That is, I was able to

determine that this study demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

After reviewing the entire Show Cause record, we find that claimant has not established a reasonable medical basis to support her claim. First, claimant does not adequately refute the findings of either the auditing cardiologist or the Technical Advisor that claimant had mild mitral regurgitation.<sup>10</sup> Both Dr. Irani and Dr. Vigilante reviewed claimant's August 19, 2002 echocardiogram and concluded that it demonstrated mild mitral regurgitation. Dr. Irani specifically noted "[m]ild [mitral regurgitation] by [transesophageal echocardiogram] with ratio likely 15%".<sup>11</sup> Neither Ms. James nor her cardiologists ever identified any particular error in either Dr. Irani's or Dr. Vigilante's conclusion. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to

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10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Report 34.

11. Similarly, we disagree with claimant's contention that Dr. Irani failed to "give the necessary deference" to her attesting physician. Nor did Dr. Irani merely "substitute[] his" opinion for that of the attesting physician. Instead, Dr. Irani specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

meet her burden of demonstrating that there is a reasonable medical basis for her claim.

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for Dr. Jensen's representation that the echocardiogram of August 19, 2002 demonstrates moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. Here, both the auditing cardiologist and Technical Advisor concluded that claimant's echocardiogram demonstrates only mild mitral regurgitation. Adopting claimant's argument would allow a claimant to recover full Matrix Benefits with an RJA/LAA ratio less than the amount required by the Settlement Agreement. This result would render meaningless this critical provision.<sup>12</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for her attesting physician's opinion that claimant's August 19, 2002 echocardiogram demonstrates moderate mitral regurgitation.<sup>13</sup> Accordingly, we will affirm the Trust's

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12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

13. Because claimant's August 19, 2002 echocardiogram demonstrates only mild mitral regurgitation, she is entitled to receive only Matrix B-1 benefits. Thus, we need not resolve the  
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denial of the claim of Ms. James for Matrix A-1 benefits and the related derivative claim submitted by her spouse.

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13. (...continued)  
issues surrounding claimant's June 4, 2002 echocardiogram.